Monitoring Medicaid Managed Care Organizations (MCOs) and Prepaid Inpatient Health Plans (PIHPs):

A protocol for determining compliance with Medicaid Managed Care Proposed Regulations at 42 CFR Parts 400, 430, et al.

Department of Health and Human Services
Centers for Medicare & Medicaid Services

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Attachment B - continued

I. Purpose and Origin of the Protocol

PURPOSE OF THE PROTOCOL

The Balanced Budget Act of 1997 (BBA) requires State Medicaid agencies that contract with Medicaid managed care organizations (MCOs) to develop a State quality assessment and improvement strategy that is consistent with standards established by the Department of Health and Human Services (DHHS).[1] A final regulation issued in the Federal Register on June 14, 2002 specifies these standards.[2] The BBA also required DHHS to develop protocols to be used in independent, external reviews of the quality and timeliness of, and access to, care and service provided to Medicaid beneficiaries by Medicaid MCOs. In a separate NPRM published on December 1, 1999, DHHS identified monitoring of MCO and Prepaid Health Plan (PHP) compliance with the BBA-required quality standards as one of the activities to be addressed by the protocols.

Private accreditation organizations, State licensing and Medicaid agencies, and the Federal Medicare program all recognize that having standards for quality health care is only the first step in promoting safe and effective health care. Making sure that the standards are followed is the second step. This protocol describes that second step: How State Medicaid agencies or their contractors can determine, in a manner consistent with standard industry practices, the extent to which MCOs and Prepaid Inpatient Health Plans (PIHPs) comply with the Federal quality standards for MCOs and PHPs.

ORIGIN OF THE PROTOCOL

To develop this protocol, approaches used by the following organizations during the period January 1999 to January 2000 to determine compliance with their MCO standards were reviewed.

- **American Accreditation Health Care Commission/URAC - National Network Accreditation Program**

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[1]The requirement for these standards is located in section 1932(c) (1) (B) of the Social Security Act.

[2]DHHS first proposed regulations to specify these standards in a Notice of Proposed Rulemaking (NPRM) published in the Federal Register on September 29, 1998; and in a final regulation issued in the Federal Register on January 19, 2001. The final regulations published in the Federal Register on June 14, 2002 amended the Medicaid managed care regulations published on January 19, 2001.

- **Health Care Financing Administration - Medicare Contractor Performance Monitoring System**

- **Joint Commission on Accreditation of Healthcare Organizations (JCAHO) - Accreditation Program for Health Care Networks**

- **National Committee for Quality Assurance (NCQA) - Accreditation Program for Managed Care Organizations**

Summaries of their compliance determination procedures are found in Attachment A. An analysis of their procedures for evaluating compliance with standards similar to those in the Medicaid Managed Care Final Rule provided the basis for this protocol. This comparative analysis identified two common approaches that each of the noted reviewing bodies utilized to determine compliance with regulations and standards: 1) document review and 2) interviews with organization staff.

II. Overview of the Protocol

The protocol uses two main sources of information to determine compliance with the proposed BBA requirements: 1) document review and 2) interviews with MCO/PIHP personnel. *Individually*, document review and interviews do not always give a complete picture of an organization's compliance with regulatory provisions. However, when combined, they can lead to a better understanding of organization performance. This protocol describes how to efficiently combine and conduct document review and interview activities in order to determine the extent to which an MCO/PIHP complies with the BBA regulatory provisions.

When monitoring for compliance with specific regulatory requirements, it generally is inefficient to monitor compliance by focusing on one regulatory provision at a time. Instead, grouping document review and interview activities together in some logical fashion produces a more efficient evaluation process, and can lead to evaluation results that better reflect an organization's overall performance. Because of this, the protocol activities are not organized by regulatory provisions, but by the groups of documents to be reviewed and interviews to be conducted. All regulatory provisions are addressed in this approach. Parties interested in a "crosswalk" that shows how each regulatory provision is addressed in the interviews and document review should refer to Attachment B. This attachment presents each individual regulatory provision and its corresponding document review and interview activities used to assess MCO and PIHP compliance.

Document Review

The protocol groups documents to be reviewed according to subject matter. This will assist MCOs/PIHPs to identify what is to be evaluated. This should also assist reviewers to identify all issues to which a particular document or group of documents pertain, allowing one evaluation of the document to address multiple requirements. The protocol references documents by their generic name or title. Organizations may refer to documents by various names. Therefore, the name and title of a document are not necessarily what is important to a certain extent, as much as the presence or absence of evidence within a document is what is important when determining compliance. The content for which the document is being reviewed is identified for individual regulatory provisions or groups of related regulations. Attachment B lists documents to be reviewed under each regulatory provision for which they may provide evidence of compliance.

Interviews

While document review is an important part of determining compliance, understanding the document content and performance of procedures outlined in the documents typically can only be determined by talking with MCO/PIHP personnel. Therefore, interaction with MCO/PIHP staff is required in order to obtain a complete picture of the degree of compliance with requirements. Interviews are an effective way of gathering data from people and are the second component of this protocol.

Interviews provide clarification. They can reveal the extent to which what is documented is actually implemented. Interviews also provide an opportunity to explore any issues that were not fully addressed in documents, and also provide a better understanding of MCO/PIHP performance. However, the interview process can provide many logistical challenges - for both reviewers and the MCOs/PIHPs being evaluated. Because of this, it is important that the process be coordinated in order to provide the best results. Individuals typically are grouped together for interviews, based on the functions that they perform or to which they contribute in some capacity. Individuals who are anticipated as being able to enhance understanding of the MCO's/PIHP's performance are identified generically in this protocol by their title or function. As MCOs/PIHPs may use various titles and function identifiers, interviews can be conducted with individuals or groups serving in similar capacities as those typically associated with the generic definitions.

Issues to be addressed during interviews are specified in suggested or potential questions or probes. The questions or probes are not designed to be read, but rather to serve as potential guides for exploration of compliance issues. These questions or probes can and should be used in more than one interview to determine consistency of the responses. The questions or probes also should be posed in such a way that a reply by more than one participant can be expected. Open-ended questions that encourage conversation among participants in an interview are more useful than those that call for a "yes" or "no" answer.

The questions or probes for each regulatory provision or group of provisions appear in Attachment B.

Although document review and interviews are the core activities that comprise this protocol, additional processes are necessary to prepare for, and thereby effectively support and conclude the compliance determination activities. All these protocol activities are presented in the order in which they are intended to be performed. Each activity includes a description, recommendations for timing, structure and process, and when applicable, other supplemental information, such as lists or forms. The seven activities that comprise this protocol are:

1. Planning for compliance monitoring activities
2. Obtaining background information from the State Medicaid agency
3. Document review
4. Conducting interviews
5. Collecting any other accessory information (e.g., from site visits)
6. Analyzing and compiling findings
7. Reporting results to the State Medicaid Agency

III. Protocol Activities

ACTIVITY 1: Planning compliance monitoring activities

Onsite visits to MCOs/PIHPs are commonly used by organizations such as private accreditation organizations to perform quality oversight and compliance determination assessments. Onsite visits are an effective method for performing monitoring activities such as document review and interviews. Arranging an onsite visit requires careful planning in order for the effort to provide useful results. It is recommended that these activities begin anywhere from two to six months prior to the actual visit date. Steps include:

➤ **Establishing contact with the MCO/PIHP**

The success of an onsite evaluation hinges on the coordination between the evaluator and the entity being evaluated. Early contact and communication with the MCO/PIHP is necessary to plan an efficient and effective survey and therefore is a crucial step in arranging and conducting an onsite evaluation. Efforts should be made to establish and maintain consistent communication links for both the evaluator and the MCO/PIHP. When feasible, these links should be with more than a single individual. A communication plan and expectations should be outlined and followed to the extent possible.

➤ **Gathering information on the MCO's/PIHP's characteristics**

Planning and conducting an efficient and effective onsite evaluation of an MCO/PIHP requires knowledge about the entity's structure, enrolled population, providers, services, operations (e.g., locations where activities take place, contractors), resources, and delegated functions. This information may be obtainable from the State Medicaid agency, or may need to be requested directly from the MCO/PIHP. The information collected should focus on what is needed to plan for an onsite evaluation; it is not intended to be the collection of compliance information. A consistent set of information with defined uses should be identified, and methods for collection need to be established. A sample set of information might include:

- Organization name and mailing address
- Contact person's name, title, phone number, e-mail address
- Location for the onsite visit (e.g., headquarters address)
- Organizational charts or other structural descriptions of the MCO/PIHP
- Product lines offered
- Total individuals enrolled (for current and previous year) with a breakdown by product line
- Total individuals served (for current and previous year)
- Total number of network practitioners (for current and previous year) with a breakdown by type, for example, primary care, OB/GYN, and other specialties

- Total number of network organizational providers (hospitals, ambulatory care, home care, laboratories, etc.)
- Service descriptions and benefit designs available to purchasers
- Delegated activities

➢ **Determining the length of visit and the visit dates**

The length of an onsite visit will vary based on the scope of the evaluation, the number of reviewers available to conduct the visit, and characteristics of the MCO/PIHP collected in the previous step. Based on the experience of accrediting bodies that survey for compliance with standards similar to those requirements contained in the Final Rule, the estimated length for an onsite visit is generally from three to five days.

Scheduling an onsite evaluation can be accomplished by identifying a potential range of dates from which the MCO/PIHP can select specific days for their onsite visit. Since reviewer interaction with staff is a primary component of the evaluation process, it is important to provide the MCO/PIHP an opportunity to select dates that ensure the greatest availability of interview participants.

➢ **Identifying the number and types of reviewers needed**

Reviewer skills and experience will be instrumental to successful implementation of the evaluation. Effective reviewers need to have interviewing skills, and the ability to read and process a variety of data in order to make determinations of whether an MCO/PIHP is demonstrating conformity with the regulatory provisions. Knowledge or experience in State Medicaid programs and managed care in general, are highly desirable qualifications for reviewers. Reviewer orientation and training should be considered to ensure familiarity with the regulatory provisions, the evaluation process and performance expectations.

A defined number of reviewers should be assigned to conduct the onsite evaluation of an MCO/PIHP. The number should be based on the characteristics of the MCO/PIHP that is being evaluated. Conditions such as the type of MCO/PIHP, size of provider network, number of Medicaid enrollees and scope of programs being contracted for by the State Medicaid agency will be some of the determinants used in identifying the number of reviewers needed.

➢ **Establishing an agenda for the visit**

Performing an efficient and effective onsite evaluation requires a plan, or agenda. An agenda will assist the MCO/PIHP in planning for staff participation, gathering documentation, and addressing logistical issues, such as arranging locations for reviewers to conduct document review and interviews. An agenda sets the tone, as well as expectations for the onsite visit so that both the MCO/PIHP and the reviewers understand the objectives and time frames for the review. The MCO/PIHP should be consulted throughout the agenda setting process as it is in the best position to know which staff members need to be involved.

➤ **Providing preparation instructions and guidance to the MCO/PIHP**

An onsite evaluation process requires the cooperation of the MCO/PIHP being evaluated. If the MCO/PIHP is prepared for the onsite visit, reviewers can remain focused on conducting and completing the evaluation in the allotted time frame. In preparation for the onsite visit, MCOs/PIHPs should be provided with information; this should include: the scope of the evaluation to be performed, how the evaluation will be conducted, lists of documents that need to be available, instructions for the organization and presentation of documents, completion of any forms or other data gathering instruments (e.g., an Information Systems Capability Assessment - see Appendix Z), expected interview participants, administrative arrangements, and other expectations or responsibilities.

ACTIVITY 2: Obtaining background information from the State

Some provisions of the final regulations published on June 14, 2002 contain language that either required or allowed the State Medicaid agency to make certain decisions and specify certain standards or requirements for MCOs/PIHPs. This typically was done in situations in which there was felt to be a need to respond to known or potential regional, state or local practices and geographic conditions, or where the state of the art has not yet evolved to produce a single standard of care. Because of this, when assessing compliance with certain regulatory provisions, the entity conducting the compliance review will need to obtain from the State Medicaid agency any standards, requirements, or decisions pertaining to MCOs/PIHPs that the State has specified in response to the BBA regulatory requirements on the State. The following list represents a compilation of these State standards, requirements, or decisions consistent with the June 14, 2002 regulations. These standards, requirements, and decisions are also noted in Attachment B.

Subpart C--Enrollee Rights and Protections	
Regulatory Provision	**Information to Obtain from the State**

Subpart C--Enrollee Rights and Protections

Regulatory Provision	Information to Obtain from the State
438.100(b)(2)(i): Enrollee right to receive information	1) The language(s) that the State Medicaid agency has determined are prevalent in the MCO's/PIHP's geographic service area 2) Any requirements the State has issued to the MCO/PIHP specifying a standard for the reading level of written materials prepared for enrollees 3) The State's decision about whether or not the MCO is to <u>notify</u> all enrollees at least once a year of their right to request and obtain the information listed in paragraphs (f)(6) and (g) of §438.10 4) The State's decision about whether the MCO is to <u>furnish</u> to each of its Medicaid enrollees the information listed in paragraphs (f)(6) and (g) within a reasonable time after the MCO/PIHP receives, from the State or its contracted representative, notice of the recipient's enrollment 5) Information on how the State has defined a "significant change" in the information MCOs/ PIHPs are required to give enrollees pursuant to §438.10(f) and (g) 6) Whether or not the MCO/PIHP is part of a State managed care initiative that employs mandatory enrollment of beneficiaries in the MCO/ PIHP under section 1932(a)(1)(A) of the Act. If the MCO/PIHP is part of such an initiative, obtain information from the State on the State's decision about whether the State or the MCO is to provide potential enrollees with the information contained in §438.10(h). 7) If the MCO/PIHP is part of a mandatory managed care initiative AND IF the State has directed the MCO to provide comparative information on disenrollment as part of a chart-like comparison of MCOs and PIHPs, obtain the State agency's definition of "disenrollment rate" 8) Whether or not the State agency has chosen to give providers the right to challenge the failure of an MCO/ PIHP to cover a contracted service 9) Any applicable State laws on enrollee rights
438.100(b)(2)(iii): Enrollee right to receive information on available treatment options and alternatives . . . including requirements of §438.102:	Information on whether or not the MCO/PIHP has documented to the State any moral or religious objection to providing, reimbursing for, or providing coverage of, a counseling or referral

Subpart C--Enrollee Rights and Protections	
Regulatory Provision	**Information to Obtain from the State**
Provider-enrollee communications	service for a particular Medicaid service or services.

438.100(b)(2)(iv) and (v): Enrollee right to:
  - **participate in decisions regarding his or her care, including the right to refuse treatment;**
  - **Be free from any form of restraint . . . as specified in other Federal regulations.**
 	
And related:
438.6(i) Advance directives
	1) A written description of any State law(s) concerning advance directives. The written description may include information from State statutes on advance directives, regulations that implement the statutory provisions, opinions rendered by State courts and other States administrative directives. *[Note to reviewers: Each State Medicaid agency is required under Federal regulations at 42 CFR 431.20 to develop such a description of State laws and to distribute it to all MCOs. Revisions to this description as a result of changes in State law are to be sent to MCOs no later than 60 days from the effective date of the change in State law.]*
	2) Information on whether or not the MCO/PIHP has documented to the State any moral or religious objection to fulfilling the regulatory provisions pertaining to advance directives.

438.100(d): Compliance with other Federal and State laws	Obtain from the State Medicaid agency the identification of all State laws that pertain to enrollee rights and with which the State Medicaid Agency requires its MCOs/PIHPs to comply.

Subpart D: Quality Assessment and Performance Improvement	
Regulatory Provision	**Information to Obtain from the State**
438.206: Availability of services	Information on whether or not:

Subpart D: Quality Assessment and Performance Improvement	
	1) The State agency has required the MCO or PIHP to adhere to any explicit standards for provider network adequacy, such as prescribed primary physician/enrollee ratios or specialist/enrollee ratios 2) The State agency has in place any time or distance standards for beneficiary travel to access covered services in Medicaid fee-for-service 3) There are any State laws requiring MCOs and PIHPs to make specific types of providers available for the provision of certain services
438.206(c)(1): Furnishing of services and timely access	Obtain a copy of the State Medicaid agency's standards for timely enrollee access to care and services required of Medicaid MCOs and PIHPs.
438.206(c)(2): Furnishing of services and cultural considerations.	1) Descriptive information on the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds. 2) The requirements the State has communicated to the MCO/PIHP with respect to how the MCO/PIHP is expected to participate in the State's efforts to promote the delivery of services in a culturally competent manner.

Subpart D: Quality Assessment and Performance Improvement	

438.208: Coordination and continuity of care	1) Definition/specifications used by State to identify individuals with special health care needs (SHCNs).
	2) Methods used by the State to identify to the MCO/PIHP new enrollees with SHCNs.
	3) Whether the MCO/PIHP is required to screen to identify and/or assess persons with SHCNs using the State's definition of SHCNs.
	4) State requirements for MCO/PIHP care coordination programs.
	5) ***If the organization to be reviewed is a PIHP,*** whether the PIHP is required to ensure each enrollee has: A) an ongoing source of primary care appropriate to his/her needs, and B) a person/entity formally and primarily responsible for coordinating the health care services furnished to the enrollee.
	6) ***If the organization is an MCO serving enrollees also enrolled in a Medicare+Choice plan and receiving Medicare benefits,*** information about the extent to which the MCO is required to implement:
	- for enrollees determined to have ongoing special conditions that require a course of treatment or regular care monitoring, a mechanism to ensure that: (1) the enrollee may directly access a specialist (e.g., through a standing referral or approved number of visits) as appropriate for the enrollee's condition and identified needs, and (2) a treatment plan that, if required by the MCO/PIHP is developed by the specialist in consultation with the enrollee's primary care provider, and is
	   (i) developed with enrollee participation;
	   (ii) approved by the MCO/PIHP in a timely manner, if this approval is required; and
	   iii) In accord with the State's quality assurance and utilization review standards.
	- a primary care and coordination program that meets State requirements and ensures each enrollee has 1) an ongoing source of primary care appropriate to his/her needs and 2) a person or entity formally and primarily responsible for coordinating health care services furnished to the enrollee.
	7) The State's quality assurance and utilization review standards

438.210(b-e): Coverage and authorization of services, including 438.114, emergency and post-stabilization services	Obtain from the State Medicaid agency the State-established standards for MCO/PIHP processing of standard authorization decisions.

Subpart D: Quality Assessment and Performance Improvement	
438.214: Provider selection	Obtain from the State information on any credentialing, recredentialing, or other provider selection and retention requirements established by the State.
438.226: Enrollment and disenrollment, including section 438.56: Enrollment and disenrollment: Requirements and limitations	Information on: 1) Whether or not the State Medicaid agency allows the MCO or PIHP to process enrollee requests for disenrollment for cause and, if so, whether or not the State requires enrollees to seek redress through the MCO's or PIHP's grievance system before the State makes a determination on the enrollee's request. 2) A copy of the State-MCO contract provisions, which specify the methods by which the MCO or PIHP assures the State Medicaid agency that it does not request disenrollment for reasons other than those permitted under the contract.
438.228: Grievance systems	Obtain information on whether or not the State delegates responsibility to the MCO or PIHP for providing each Medicaid enrollee (who has received an adverse decision with respect to a request for a covered service) notice that he or she has the right to a State fair hearing to reconsider their request for the covered service.
438.230: Sub contractual relationships and delegation	Obtain from the State the "periodic schedule" established by the State according to which the MCO/PIHP is to monitor and formally review on an ongoing basis all subcontractors' performance of any delegated activities.
438.240: Quality assessment and performance improvement program **(a) General rules** **(b) Basic elements of MCO and PIHP quality assessment and performance improvement programs** **(d) Performance improvement projects**	Obtain from the State Medicaid agency: 1) Information on whether or not the State Medicaid agency has required the MCO's/PIHP's performance improvement projects to address a specific topic(s), or address a specific topic(s) and also use specific quality indicators identified by the State Medicaid agency 2) The State's requirements with respect to MCO/PIHP reporting of the status and results of each performance improvement project to the State Medicaid agency

Subpart D: Quality Assessment and Performance Improvement

	3) Any reports on the status and results of the performance improvement projects submitted by the MCO/PIHP in response to State requirements for reporting the status and results of each performance improvement project to the State Medicaid agency
438.240(c): Performance measurement and improvement	Obtain from the State Medicaid agency: 1) A list of all performance measures required of the MCO/PIHP by the State for the year or years for which the review is being conducted 2) The actual performance measures submitted by the MCO/PIHP to the State for the year or years for which the review is being conducted 3) Instructions from the State on whether or not the State wishes the EQRO to validate the MCO's/PIHP's submitted performance measures.
438.240(e): Program review by the State.	Determine from the State Medicaid agency whether or not the State has required the MCO/PIHP to have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement (QAPI) program and, if so, how frequently the MCO/PIHP is to make such an evaluation.
438.242: Health information systems	1) Information on whether or not the State has required the MCO/PIHP to undergo, or has otherwise received, a recent assessment of the MCO's/PIHP's health information system (IS). If the State has required or received such an assessment, obtain a copy of the IS Assessment from the State or the MCO/PIHP. Also obtain contact information about the person or entity that conducted the assessment and to whom follow-up questions may be addressed. 2) State specifications for data on enrollee and provider characteristics that must be collected by the MCO/PIHP. 3) State specifications for how MCOs/PIHPs are to collect data on services furnished to enrollees (i.e., whether or not the MCO/PIHP must collect encounter data or may use other methods). If the State allows the MCO/PIHP to use other

Subpart D: Quality Assessment and Performance Improvement	
	methods, what are the State's requirements with respect to these "other methods?" If the State requires MCOs/PIHPs to collect encounter data and report it to the State, does the State validate this data or require it to be validated? If the data is validated, obtain a copy of the most recent validation report.

Subpart F--Grievance System	
438.402: General requirements	Obtain from the State information on: 1) The time frame during which enrollees and providers are allowed to file an appeal; 2) Whether or not the State requires enrollees to exhaust MCO/PIHP level appeals prior to requesting a State fair hearing; and 3) Whether enrollees are required or permitted to file a grievance with either the State or the MCO/PIHP or both.
438.404: Notice of Action	Obtain from the State Medicaid Agency information on the time frames within which it requires MCOs/PIHPs to make standard (initial) coverage and authorization decisions and provide written notice to requesting enrollees. These time frames will be the required period within which MCOs/PIHPs must provide Medicaid enrollees written notice of any intent to deny or limit a service (**for which previous authorization has not been given** by the MCO/PIHP) and the enrollee's right to file a MCO or PIHP appeal (or request a State fair hearing if the State does not require the enrollee to exhaust MCO/PIHP level appeals prior to requesting a State fair hearing).
438.408: Resolution and notification: Grievances and appeals	Obtain from the State Medicaid Agency: 1) The State-established **standard** time frames during which the State requires MCOs/PIHPs to: - dispose of a grievance and notify the affected parties of the result; - resolve appeals and notify affected parties of the decision; and - expedite and resolve appeals and notify affected parties of the decision. 2) The methods prescribed by the State that the MCO/PIHP must follow to notify an enrollee of the disposition of a grievance. 3) Information on whether or not the State requires Medicaid enrollees to exhaust MCO or PIHP level appeals before receiving a State fair hearing.
438.414: Information about the	Obtain from the State Medicaid Agency

Subpart F--Grievance System	
grievance system to providers and subcontractors	information on: 1) Whether the State develops or approves the MCO's/PIHP's description of its grievance system that the MCO/PIHP is required to provide to all Medicaid enrollees *[Note that under regulations at §438.10(g)(1) the State must either develop a description for use by the MCO/PIHP or approve a description developed by the MCO/PIHP]* 2) If the States approves, rather than develops, the description of the MCO's/PIHP's grievance system, information on whether or not the State has already approved the MCO's/PIHP's description 3) The State-specified time frames for disposition of grievances
438.420: Continuation of benefits while the MCO or PIHP appeal and the State Fair Hearing are pending	Obtain from the State Medicaid Agency information on any time limits specified by the State that must be met by Medicaid enrollees who wish to file an appeal, request for expedited appeal or State fair hearing
438.424: Effectuation of reversed appeal resolutions	Obtain from the State Medicaid Agency information on whether the State or the MCO/PIHP is required to pay for services in situation in which the MCO or PIHP, or the State fair hearing officer reversed a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending

ACTIVITY 3: Document review

Typically, an onsite visit begins with document review. Prior to the onsite visit, the MCO/PIHP should receive from the entity conducting the compliance monitoring a list of documents needed for review. This should be accompanied by instructions on how to organize and prepare the documents for the reviewers. These instructions should request that documents remain available to reviewers for the duration of the onsite visit. Reviewers should request the MCO/PIHP to provide an orientation to the organization of their documents. Also prior to the onsite visit, reviewers should request reports on previous reviews and subsequent MCO/PIHP corrective actions in order to identify areas on which the reviewers might need to focus the current monitoring.

Prior to conducting document review, reviewers should re-familiarize themselves with the standards for which they will be evaluating compliance and the document list to determine the items of information that they should be seeking in the MCO/PIHP documentation. In instances where multiple reviewers are conducting the onsite visit, the team may want to identify in advance what issues each reviewer will take responsibility for evaluating in documents and pursuing during interviews. Pre-planning for this activity will be key to accomplishing the task.

During document review, reviewers begin the assessment of compliance with regulatory provisions, and identify issues that will be pursued during interviews. MCO/PIHP staff does not need to be present during this onsite activity, but should be available if reviewers have questions or difficulty locating a particular document or item of information.

During the review of documentation, reviewers should:
- Take notes that will assist in making determinations about compliance with the regulatory provisions and support the completion of a Documentation and Reporting Tool such as that provided in Attachment C;
- Identify topics or issues that need clarification or follow-up during interviews;
- Identify items of information that were not available or located in documents to provide the MCO/PIHP an opportunity to respond; and
- Identify specific document content for discussion at an interview to provide the MCO/PIHP an opportunity to prepare participants with copies or to identify additional participants that may be necessary for the discussion.

A list of the documents needed to evaluate compliance with the Medicaid regulatory provisions follows. Documents are identified using generic names, except in instances where the regulatory provisions refer to and require a specific document be present and reviewed for content. The documents in the list are grouped by subject matter, with the regulatory provision numbers noted to aid in identifying where knowledge gained by reviewing the documents can be applied. This does not imply that the document cannot be used as a data source for addressing other provision issues, or that it should be the sole source of data in evaluating compliance with the provisions noted. Reviewers should use Attachment B in conjunction with this list to identify specific information that needs to be located in these documents.

Document	Applicable Regulatory Provision (Full regulatory citations and provisions are located in Attachment B)
Administration/Managerial	
Service planning documents and provider network planning documents (e.g., geographic assessments, provider network assessments, enrollee demographic studies, population needs assessments)	438.206(b)(1) through (5) 438.206(c) 438.214
Service availability and accessibility expectations and standards	438.206(b)(1) and (2) 438.206 (c)
Other performance standards and quality indicators established by the MCO/PIHP	438.206(b) and (c)
Any measurement or analysis reports on service availability and accessibility	438.206(b) and (c)
List of all care and service providers in the MCO's/PIHP's network (may be the same as the provider directory)	438.206(b)(1) and (2)
Organization strategic plans	438.206(b)(1) 438.206(c)
Administrative policies and procedures	438.206(b)
Procedures and methodology for oversight, monitoring, and review of delegated activities	438.214 438.230
Contracts or written agreements with organizational subcontractors	438.210 438.214 438.230 438.414
Completed evaluations of entities conducted before delegation is granted	438.210 438.214 438.230 438.414
Ongoing evaluations of entities performing delegated activities	438.230

Document	Applicable Regulatory Provision (Full regulatory citations and provisions are located in Attachment B)
QAPI program description	438.240(a) through (d)
QAPI project descriptions, including data sources and data audit results	438.236(c) 438.240(b)(2) and (3) 438.242
QAPI project quality indicators, the selection or development criteria, and processes for selection or development	438.240(d)
QAPI program evaluation	438.240(e)
QAPI data analysis and reports	438.240
Performance measures produced by the MCO/PIHP	438.240
Policies and procedures related to data collection and data quality checks for QAPI projects	438.240
Policies and procedures for researching, selecting, adopting, reviewing, updating and disseminating practice guidelines	438.236(a) through (c)
Practice guidelines adopted by the MCO/PIHP	438.208 438.236(a) and (b)
Medicaid and other enrollee grievance and appeals data	438.210 438.242
Medicaid and other enrollee survey results	438.10 438.100 438.206(c)
Utilization Management	
Utilization management policies and	438.206(b)(2) through (5)

Document	Applicable Regulatory Provision (Full regulatory citations and provisions are located in Attachment B)
procedures	438.210 438.236 438.240
Coverage rules and payment policies	438.114 438.210
Data on claims denials	438.210 438.404
Service authorization policies and procedures	438.206(b) 438.210
Policies and procedures for notifying providers and enrollees of denials of service	438.210
Analytic reports of service utilization	438.242
Policies and procedures related to practice guidelines, including selection criteria, involvement of practitioners in review and adoption process, schedule for updating, etc.	438.236
Processes used to review practice guidelines for consistency with other criteria and services of the MCO/PIHP	438.236(c)
Information Systems	
Information systems capability assessment reports	438.242(a) and (b)

Document	Applicable Regulatory Provision (Full regulatory citations and provisions are located in Attachment B)
Policies and procedures for auditing data or descriptions of other mechanisms used to check the accuracy and completeness of data (internally generated and externally generated data)	438.242
Completed audits of data or other evidence of data monitoring for accuracy and completeness both for MCO data and contractor (delegate) data	438.240 438.242
Provider/Contractor Services	
Provider/Contractor Services policies and procedures manuals	438.6 438.100(a)(2) 438.208 438.242
Provider contracts	438.6 438.100(a) and (b) 438.102 438.206(b) and (c) 438.208 438.242 438.414
Provider/Contractor procedure manuals	438.6 438.100(a)(2) 438.206(b)(2) 438.206(c) 438.208 438.236(c) 438.414
All other written forms of standard provider communication	438.236(c)
Provider/Contractor oversight and evaluation policies and procedures, audit tools	438.100(a)(2) 438.206(c)
Provider/Contractor files, 15-20 individual	438.6

Document	Applicable Regulatory Provision (Full regulatory citations and provisions are located in Attachment B)
health care professional files, and 15-20 institutional provider files	438.214
Provider/contractor orientation and education curricula	438.100(a)(2)
Credentialing committee or other provider review mechanism meeting minutes	438.214
Sample of files of practitioners who have not been appointed or reappointed	438.214
Enrollee Services	
Medicaid enrollee services policies and procedures	431.51(a)(4) through (a)(6) 438.6 438.10(a) through (g) 438.100(b)(2) 438.106 438.108 438.114 438.206(b)(2) through (b)(5) 438.206(c) 438.208
Statement of enrollee rights	431.51(a)(4) through (a)(6) 438.6 438.10 (a) through (h) 438.100 438.114 438.206(b)(3) through (b)(5)
Medicaid enrollee marketing materials	431.51(a)(4) through (a)(6) 438.10(a) through (h) 438.100(b)(2)(i) 438.104
Medicaid marketing plans, policies and procedures	438.10(a) through (h) 438.100(b)(2)(i) 438.104
Medicaid enrollment and disenrollment policies and procedures	438.10(a) through (f) 438.56(b) through (e)i 438.100

Document	Applicable Regulatory Provision (Full regulatory citations and provisions are located in Attachment B)
	438.208 438.226
Medicaid enrollment data	434.242
Medicaid enrollee handbooks	438.6 438.10(a) through (d) 438.10(f) through (h) 438.100 438.206(b)(2) through (5) 438.206(c) 438.208
Medicaid provider directory	438.10 (b) through (e) 438.10(f)(6) 438.206(b)
Medicaid enrollee orientation curriculum	438.10(b) through (d) 438.10(f) 438.10(g) 438.100 438.206(b)(2) through (5)
Enrollee health education planning and program content	438.236(c)
Medicaid enrollee grievance and appeals policies and procedures	438.10(f) and (g) 438.56 438.100 438.206(c) 438.228 438.402(a) and (b) 438.404 438.406(a) and (b) 438.408(a) through (e) 438.410(a) through (c) 438.420 438.424(a) and (b)
Medicaid enrollee grievance and appeal tracking reports	438.228 438.408(a) through (e) 438.410(a) through (c)
Care coordination policies and procedures,	

Document	Applicable Regulatory Provision (Full regulatory citations and provisions are located in Attachment B)
and enrollee records	438.208
Sample of Medicaid enrollee records	438.208
Staff Planning, Education, Development and Evaluation	
Staff handbooks	438.10 438.100
Staff orientation and training curriculum	438.10 438.100

ACTIVITY 4:   Conducting interviews

Purpose of Interviews
Data gathered from interviews should supplement and verify what is learned during document review. Interview participants provide clarification and confirm that what is documented is what is carried out in practice, thus supplying further evidence that the MCO/PIHP understands the regulatory provisions and is able to demonstrate compliance in its performance.

Interview Planning
The following descriptions of interviews are intended to serve as interview templates, recognizing that, in practice, interviews should be customized to the MCO/PIHP being evaluated. This customization should be based on information that is known about the MCO/PIHP from pre-onsite data gathering activities (characteristics, population demographics, etc.) and from what reviewers learned from the document review. As a result, effective interviewing requires advance planning. This planning is an informal, but important, process to achieve the MCO/PIHP evaluation objectives. Planning should include:

- Preparing a list of issues that need to be addressed in each interview, based on the regulatory provisions (Attachment B), organization characteristics, and information gathered during document review.
- Reviewing the MCO's/PIHP's anticipated participants for the interview and identifying topics that will engage as many individuals in the discussion as possible.
- When multiple reviewers are assigned to an MCO/PIHP, reviewers should determine what role each would play during the interviews, for example, interviewer or note-taker. Although pre-established as primary roles, this does not preclude designated note-takers from sharing in the interviewing of participants or preclude interviewers from taking notes.

It is recommended that document review not be performed during scheduled interview time. If interview participants bring documents with them, they should be reviewed following the interview or at another time. The exception would be in those instances in which the documents are vital to the discussion and where the review can be interactive and involve all participants.

Interview Participants
Interviews should be scheduled in coordination with the MCO/PIHP (See Activity 1: Evaluation Planning) in order to gain the greatest participation of staff and other individuals. Interviews should be conducted with groups, rather than with single individuals. Rarely is one individual within the MCO/PIHP solely responsible for a particular function. Therefore, it is recommended that at the interview several people represent the differing functions, services, or departments of the MCO/PIHP. Cross-functional/service/department interviews are also beneficial to the data gathering process. What one area does not know, another may, and the interview then becomes a learning opportunity for the MCO's/PIHP's staff as well.

The following group interviews should be conducted:

- MCO/PIHP leadership
- MCO/PIHP information system personnel
- Quality assessment and performance improvement program personnel
- Provider and contractor services staff
- Enrollee services staff
- Utilization management staff
- Medical Director
- Case managers and care coordinators

Additionally, MCO/PIHP providers could be interviewed if time and resources permit.

Conducting the Interview

During interviews, reviewers should:
- Begin with brief introductions of themselves and MCO/PIHP participants,
- Share with the participants the interview goals based on the planning outline,
- Maintain control of the interview discussion, politely redirecting participants when necessary,
- Remain sensitive to the time (e.g., begin and end as close to the times noted on the agenda),
- Be attentive to participants and listen carefully; summarize or restate participant responses to ensure understanding,
- Take notes as needed for use in completing a Documentation and Reporting Tool (such as that in Attachment C) or to be reviewed for other interviews or to confirm document findings,
- Review documents that participants bring to the interview (at the end, or interactively during),
- Conclude the interview with a review of the outlined goals so that all present may determine if they have been met.

Interview content

Descriptions of each group interview follows. Each description includes:
- the purpose for the interview;
- suggested interview participants (as described in Attachment B); and
- potential questions/probes related to the subject matter of the regulatory provisions (as described in Attachment B) for use in prompting discussion.

Organization Leaders Interview

A. Description/Purpose/Recommended Participants

The leadership interview is an opportunity to talk with the senior representatives of the MCO/PIHP about the following Medicaid managed care requirements.

- Enrollee rights
- Enrollee information
- Availability of services (e.g., delivery network, provider credentialing, hours of operation and emergency services)
- Timely access to care
- Enrollees with special health care needs
- Cultural considerations
- Continuity and coordination of care
- Delegation
- Practice guidelines
- Quality assessment and performance improvement
- Health information systems
- Complaints and grievances

At a minimum, the following representatives of the MCO's/PIHP's leadership should be present:

- Chief executive officer (CEO);
- Chief operating officer (COO), when applicable;
- Chairman of the governing body, or a representative, when applicable;
- Medical director;
- Chief elected or appointed officer of the MCO/PIHP's licensed independent practitioners (where found);
- Quality improvement committee chairperson;
- Quality improvement program director or coordinator; and
- Human resources leader.

As determined by the CEO, other senior staff of the MCO/PIHP may also be in attendance. However, attendance at this interview should be carefully limited in order to foster candor and the free exchange of information.

B. Potential Questions to Ask

438.100 and 438.10--Enrollee right to information
1. What information is your MCO/PIHP required to disseminate to Medicaid enrollees? How often is your MCO/PIHP required to make this information available?

2. How does your MCO/PIHP give each enrollee written notice of any change (that the State defines as "significant") in the information specified above, at least 30 days before the intended effective date of the change? How does the State define "significant"? Have you made any such "significant" changes in the last year?

3. How does your MCO/PIHP give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who receives his or her primary care from, or is seen on a regular basis by, the terminated provider? Have you terminated the contract of any providers in the last year?

4. How do you ensure that your staff and affiliated providers comply with Federal and State laws that pertain to enrollee rights?

438.100--Enrollee right to respect, dignity, privacy
1. How does the MCO/PIHP ensure that its own facilities and those of its affiliated providers comply with enrollee rights such as treatment with respect, dignity, and consideration for privacy, confidentiality of information? Provide examples.

2. What processes are in place to ensure that staff members observe the MCO's/PIHP's policies and procedures on privacy and confidentiality of enrollee information?

3. What does the MCO/PIHP do to raise staff awareness of its policies on nondiscriminatory behavior towards enrollees? How is staff monitored to determine that they comply with these policies?

438.100 and 438.102--Enrollee right to receive information on available treatment options
1. Does your MCO/PIHP have any moral or religious objection to providing, reimbursing for, or providing coverage of, a counseling or referral service for a particular Medicaid service or services? If so, how do you inform potential enrollees and current enrollees of this?

2. How does the MCO/PIHP ensure that providers share information on available treatment options and alternatives with enrollees? Does this include alternatives and options that are outside, as well as within, the Medicaid contract's scope of benefits?

3. What steps does the MCO/PIHP take to ensure that enrollees receive information on available treatment options and alternatives *in a manner appropriate to their condition and ability to understand?*

438.100 and 438.6--Enrollee right to participate in decisions regarding his/her health care and advance directives.

1. To what extent does the MCO/PIHP allow enrollees to participate in care and treatment decisions? Describe.

2. Does the MCO have any limitations in implementing State and Federal laws pertaining to advance directives? If so, what are these?

438.100--Compliance with other Federal and State laws.

1. What steps do MCO/PIHP leaders take to ensure compliance with Federal and State laws on enrollee rights?

2. Has the MCO/PIHP ever been found non-compliant with any Federal and State laws on enrollee rights? If yes, in what area, and what steps were taken to clear the violation?

3. If a provider/contractor is found to be in violation of any Federal and State laws on enrollee rights, how does the MCO/PIHP respond?

4. To what extent does the MCO/PIHP orient new staff to Federal and State laws on enrollee rights that must be observed during day-to-day operations? How does the MCO/PIHP remind staff of the importance of observing these laws during interactions with other employees and with enrollees?

5. Describe the steps taken by the MCO/PIHP when staff report, or are involved in a violation of Federal or State laws on enrollee rights.

438.206--Availability of services.

1. Describe the MCO's/PIHP's process for assessing the needs for providers to deliver each type of covered service and need for major specialties within each type. What issues were considered in the assessment process?

2. How does the MCO/PIHP determine the adequacy of its network to serve its Medicaid enrollees?

3. What assumptions and methodologies are used to project the number, type (in terms of training, experience, and specialization) and location of primary care providers and specialists necessary to serve its anticipated Medicaid enrollees?

438.206(b)(3) through (5)--out-of-network providers.
1. Approximately what proportion of Medicaid enrollee provider encounters are made to out-of-network providers? If this is a significant percent, what are the reasons for this?

2. How do you pay out-of-network providers? Do you receive claim, encounter data from out-of-network providers similar to the claim, or encounter data that you receive from your network providers?

3. How does your MCO/PIHP ensure that any costs to the Medicaid enrollee for out-of-network services is no greater than the costs the Medicaid enrollee would incur if they used a network provider for the same service?

438.206(c)(1)--Furnishing of services and timely access.
1. Describe how the MCO/PIHP monitors for compliance with its Medicaid standards for timely access to care and services.

2. How does the MCO/PIHP ensure the 24 hours per day, 7 day per week availability of Medicaid services included in its contract with the State when medically necessary?

3. How does the MCO/PIHP determine that the individual and institutional providers it contracts with have sufficient capacity to make services available when medically appropriate 24 hour per day, 7 days per week to Medicaid enrollees?

4. How does the MCO/PIHP ensure that its provider network's hours of operation do not discriminate against Medicaid enrollees (i.e., are not different for Medicaid enrollees than for commercial enrollees)?

5. How big of a problem is inappropriate use of emergency rooms by your Medicaid enrollees?

6. What was the volume of denied claims for emergency and post-stabilization services in the most recent year?

438.206(c)(2)--Cultural considerations.
1. What have been the State Medicaid agency's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds? How has your MCO/PIHP participated in these efforts? What documentation exists describing your efforts and the results of your efforts?

438.208--Coordination and continuity of care.
1. How are "individuals with special health care needs" defined by the State Medicaid agency? Has your MCO/PIHP developed any other operational definition or definitions of individuals with special health care needs? If yes, what is/are these and how were they developed? How do they differ from the State definition?

2. Does the State Medicaid agency require your MCO/PIHP to screen Medicaid enrollees to identify those with special health care needs?

3. How are individuals with special health care needs - including both individuals with special health care needs identified by this MCO/PIHP and those identified by the State Medicaid agency or its agent - identified and tracked within your MCO/PIHP?

4. Does the State Medicaid agency require your MCO/PIHP to assess Medicaid enrollees with special health care needs? If yes, how are these activities conducted?

5. Who may serve as enrollee primary care providers?

6. What steps does the MCO/PIHP take to promote Medicaid enrollees' ongoing relationship with a usual source of primary care?

7. What process(es) is (are) used to coordinate services for enrollees? Are there different types of care coordination mechanisms for different types of enrollees? If so, what are these?

8. If your MCO/PIHP establishes separate coordination of care for medical services and mental health and substance abuse services, how does it ensure exchange of necessary information between providers?

9. How does the MCO/PIHP ensure coordination of its services with services enrollees may receive from other MCOs or PIHPs?

10. Under what circumstances may Medicaid enrollees have direct access to specialists?

11. How does your MCO/PIHP manage the provision or any specialty care services currently not provided in-network?

12. Does your MCO/PIHP require written treatment plans to be developed for enrollees? If yes, under what circumstances are written treatment plans required?

438.210 and 438.114--Coverage and authorization of services, including emergency and post-stabilization services.
1. How big of a problem is inappropriate use of emergency rooms by your Medicaid enrollees?

2. Has your MCO/PIHP investigated a potential relationship between inappropriate emergency room use and enrollee access to routine and urgent care?

3. What was the volume of denied claims for emergency and post-stabilization services in the most recent year?

438.214 and 438.12--Provider selection and non-discrimination.
1. What is the basis or criteria used to determine individual provider participation in the MCO's/PIHP's network?

2. What is the basis or criteria used to determine institutional or other non-individual practitioner participation in the MCO's/PIHP's network?

3. What types of providers are subject to the MCO's/PIHP's credentialing process?

4. Describe the provider credentialing process used by the MCO/PIHP.

5. What steps does the MCO/PIHP take to ensure that it does not employ or contract with providers who have been excluded from participation in Federal health care programs?

6. What steps does the MCO/PIHP take to ensure that providers who serve high-risk or costly populations are not discriminated against in the selection process, and when considering reimbursement and indemnification?

7. What criteria is the basis for denial of provider participation in the MCO's/PIHP's network?

438.228--Grievance systems.
1. How does your MCO/PIHP track requests for covered services that your MCO/PHP or its providers has denied?

2. What was the volume of denied claims for services in the most recent year?

3. How do you ensure that Medicaid enrollees who were denied services were notified of their right to a State fair hearing?

438.230--Sub contractual relationships and delegation.
1. Which of the following **OR OTHER** activities are performed by (and thereby delegated to) contractors?

- establishment or maintenance of your provider network,
- provider credentialing,
- initial assessments of enrollees,
- care coordination,
- service authorization,
- providing information to enrollees,
- grievance systems,
- quality assessment and performance improvement,
- performance measurement,
- information systems management,
- others

2. What steps does your MCO/PIHP take to determine that an entity to which functions will be delegated is capable of performing the function? Describe any such evaluation process that your MCO/PIHP has in place.

3. Describe the MCO's/PIHP's process for identifying and selecting contractors? How is it determined that a contractor has the ability to perform the activities that are to be delegated?

4. How does your MCO/PIHP determine who will monitor and review delegate activities? How often does delegate evaluation occur? Who in your MCO/PIHP is presented with evaluation results? Who in your MCO/PIHP takes action on evaluation results?

5. For <u>each</u> of the activities that have been delegated, describe the review methodology adopted by your MCO/PIHP to oversee entities that have been delegated this activity through contracts or agreements. Has the methodology been effective in determining delegate compliance with your MCO's/PIHP's performance expectations?

438.236(b)--Practice guidelines: adoption
1. What organizational component is responsible for the adoption of practice guidelines used by your MCO/PIHP?

2. How does your MCO/PIHP establish priorities for adoption of practice guidelines?

3. What guidelines has your MCO/PIHP adopted?

4. By what process were they adopted?

5. To what extent are your MCO's/PIHP's guidelines "evidence-based"?

6. How does your MCO/PIHP consider the enrolled Medicaid population's health needs in the adoption of practice guidelines?

7. How are affiliated providers consulted as guidelines are adopted and re-evaluated?

8. What mechanism(s) does your MCO/PIHP have for periodically evaluating and updating the guidelines it has adopted?

438.236(c)--Practice guidelines: dissemination and application
1. How are practice guidelines disseminated to providers?

2. When and how are guidelines disseminated to enrollees and potential enrollees?

3. To what extent are the practice guidelines adopted by your MCO/PIHP a component of your MCO's/PIHP's QAPI program?

4. Is there an interface between the QAPI program and practice guidelines adoption process?

5. What steps are taken to ensure that decision-making in the areas of utilization management or coverage determinations and other functional areas are consistent with the adopted practice guidelines?

438.240--Quality assessment and performance improvement program.
1. How does your MCO/PIHP define enrollees with "special health care needs"? How are these enrollees identified/ tracked within your MCO/PIHP?

2. How does your MCO/PIHP assess the quality and appropriateness of care furnished to enrollees with special health care needs?

438.240(e)--Quality assessment and performance improvement program: Program review by the State.
1. Does the MCO/PIHP evaluate the effectiveness of its quality assessment and performance improvement program? How often?

2. What were the findings of the MCO's/PIHP's most recent self-evaluation of its QAPI? What action did the MCO/PIHP take as a result of these findings?

438.242--Health information systems.
1. Describe the types of data collection systems that are in place to support the clinical and administrative operations of your MCO/PIHP. Specifically, what data is routinely collected to support utilization management, grievance systems, and enrollment services?

2. What processes are in place to obtain data from all components of your network (e.g., health care facilities, physician, and laboratories)? To what extent does your MCO/PIHP require and receive data in standardized formats? Are there any components of your network from which you do not receive standardized (or any) information on services?

3. How are enrollee and provider data collected and integrated across all components of your MCO's/PIHP's network? How is this used to produce comprehensive information on enrollee needs and utilization and to otherwise support management?

438.402--Grievance system: general requirements.
1. Who in the MCO/PIHP is responsible for the development and oversight of the appeals and grievance resolution process and access to State fair hearings?

2. What have been the volume of appeals/grievances/requests for State fair hearings in the past year and the most common areas of concern expressed by Medicaid enrollees? How has the MCO/PIHP addressed these concerns?

3. Describe the notice and appeals process for adverse actions on enrollee requests for services or payment. Elaborate on the particular steps, including time frames.

438.406--Handling of grievances and appeals.
1. To what extent does your MCO/PIHP provide Medicaid enrollees with assistance in completing forms and taking other procedural steps in the grievance and appeal process? How does it do this?

2. How does your MCO/PIHP treat oral requests by Medicaid enrollees to appeal actions?

3. As part of an appeal, to what extent do enrollees and their representatives have an opportunity to:
   - Present evidence, and
   - examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.
4. What are the qualifications and credentials of individuals who make decisions on grievances and appeals? How does the MCO/PIHP ensure that these individuals--
   - were not involved in any previous level of review or decision-making; and
   - If deciding any of the following, have the appropriate clinical expertise in treating the enrollee's condition or disease.
      (A) An appeal of a denial that is based on lack of medical necessity.
      (B) A grievance regarding denial of expedited resolution of an appeal.
      (C) A grievance or appeal that involves clinical issues?

5. Is there a process in place to monitor either the appeal and grievance process or the areas of concern identified by enrollee appeals and grievances?

438.408--Resolution and notification: Grievances and appeals.
1. Approximately how many grievances did the MCO/PIHP receive in the most recent reporting year?

2. Approximately how many appeals did the MCO/PIHP receive in the most recent reporting year?

3. Approximately what percent of notices of action on requests for service authorization or payment by Medicaid enrollees are appealed to the MCO/PIHP?

4. Approximately what percent of notices of action on requests for service authorization or payment by Medicaid enrollees are appealed to the State fair hearing process? Approximately what percent of these are overturned by the State?

438.410--Expedited resolution of appeals.
1. Is there a process in place for those instances when an enrollee's health condition requires expedited resolution of an appeal? Describe this process. What are the time frames for this process?

2. Are physicians allowed to request expedited appeals on behalf of an enrollee? How does the MCO/PIHP protect physicians who make such requests?

438.414--Information about the grievance system to providers and subcontractors.
1. Who in your MCO/PIHP has responsibility for the proper functioning of the grievance process and the authority to require corrective action?

2. Did your State Medicaid agency develop or approve the description of your MCO's/PIHP's grievance system provided to Medicaid providers? Which, develop or approve? If it approved your description, how is the State's approval documented?

438.416--Recordkeeping and reporting requirements: Grievances and appeals.
1. Where in your MCO/PIHP are records on Medicaid enrollee grievances and appeals kept?

Health Information Systems Staff Interview

A. Description and Purpose

This interview will assess the MCO's/PIHP's information management function and how it relates to and supports the other functions of the organization, such as planning and operations, quality assessment and improvement program activities, care coordination, etc.

The interview should include MCO/PIHP staff responsible for health information systems issues at the MCO/PIHP. It should not be limited to just those responsible for technology implementation, but should include staff that are responsible for the quality of information, movement of information, sharing of information, and information policy and procedure development and implementation.

Interviews with the Chief Information Officer (CIO) and selected health information systems staff of the MCO/PIHP will address the following:

1. Validation and clarification of an Information Systems Capability Assessment (see Appendix Z) either completed within the past two years or newly completed as a part of this compliance review,
2. The MCO's/PIHP's assessment of its information needs,
3. The extent to which the health information systems process is planned and designed to meet those needs,
4. How data are defined and captured across the MCO/PIHP,
5. How data transmission and integration take place across the MCO/PIHP,
6. How enrollee-specific data and information are made available when and where needed by the MCO's/PIHP's provider network,
7. How the MCO/PIHP makes available and uses needed aggregate data and information, and
8. How the MCO/PIHP meets external reporting needs.

This is also an opportunity to explore the extent to which the health information needs of the entire MCO/PIHP and provider network are measured, assessed, and, as indicated, improved.

B. Potential Questions to Ask

A copy of an Information Systems Capability Assessment (ISCA) (see Appendix Z) that either has been completed in the last two years by an independent organization reviewing the MCO/PIHP or has been completed by the organization conducting this compliance review, should be obtained. During this interview, validate the information provided about the MCO/PIHP on the ISCA, explore any areas of concern, and gather missing or additional information for use in evaluating standards compliance, paying particular attention to how data are defined and captured across the MCO/PIHP and how data transmission and integration takes place across the MCO/PIHP. The findings of the ISCA will serve as a guide to conducting this

interview, whether or not the entire Appendix Z protocol is being followed. Questions to be asked are dependent upon the findings of the ISCA, however, some common questions to be asked include:

1. What are the findings of the most recent assessment of the MCO's/PIHP's information systems capacity? What are your IS' strengths and weaknesses?

2. What has the MCO/PIHP done to address IS problem areas?

3. What information needs does your MCO/PIHP have that are not currently met by your present IS? What has the MCO/PIHP done to address these needs?

4. Is the data collected from network providers on services to enrollees subject to accuracy and timeliness checks?

5. Describe procedures used to screen all data, both internal and external, for completeness, logic, and consistency.

6. How is enrollee-specific data and information made available when and where needed by the MCO's/PIHP's provider network?

Additional questions should be asked to validate and gain greater understanding of the MCO's/PIHP's information system and how it is used in the support of regulatory requirement. Potential questions to be asked of the Chief Information officer and Information Systems staff include:

438.206 Delivery network
1. How does your IS track services provided by and/or reimbursed to out-of-network providers?

2. Is there any routinely collected and available data on use of out-of-network providers (excluding Point of Service-related use)? Is data on use of out-of-network providers separately available for Medicaid enrollees?

438.242 Health information Systems
1. Is the data collected from network providers on services to enrollees subjected to accuracy and timeliness checks?

2. Describe procedures used to screen all data, both internal and external, for completeness, logic, and consistency.

Quality Assessment and Performance Improvement Program Interview

A. Description and Purpose

This interview with quality improvement program leaders and staff provides an opportunity to gain a more thorough understanding of the approaches and processes used by the MCO/PIHP to assess and improve quality.

B. Potential Questions to Ask

438.206(c) Furnishing of services-timely access
1. Have any recent QAPI activities been implemented to monitor the MCO's/PIHP's compliance with its established standards for timeliness of access to care and member services?

2. What are the results of these QAPI activities?

438.214 Provider selection
1. What type of information is generated through the quality improvement program to support recredentialing of individual practitioner providers?

2. What types of information does the quality improvement program provide to support the recredentialing of institutional and other non-practitioner providers?

438.236 Practice guidelines
1. How does the QAPI program interface with the administrative function responsible for adopting practice guidelines?

438.240 Quality assessment and performance improvement program
1. Does the State require your MCO/PIHP to address a specific topic or topics and/or indicators in your performance improvement projects? If yes, what types of projects are required?

2. How does your MCO/PIHP detect over- and under-utilization? Provide examples of how your quality assessment and improvement program has monitored to detect under- and over-utilization

3. How does your MCO/PIHP define enrollees with "special health care needs"? How are these enrollees identified/ tracked within your MCO/PIHP?

4. How does your MCO/PIHP assess the quality and appropriateness of care furnished to enrollees with special health care needs? Provide examples.

5. Does the MCO/PIHP evaluate the effectiveness of its quality assessment and performance improvement program? How often?

6. Describe the evaluation process. What aspects of the program are encompassed in the evaluation?

7. What were the findings of the MCO's/PIHP's most recent self-evaluation? What action did the MCO/PIHP take as a result of these findings?

8. Is the evaluation conducted to meet the State's requirements, and if so, what is reported to the State and how often?

438.242 Health information systems
1. How are enrollee and provider data from all components of your MCO's/PIHP's network used in your MCO's/PIHP's quality assessment and performance improvement program? Are there any components in your network for which you do not have adequate enrollee utilization and provider data?

438.406 Handling of grievances and appeals
1. Is there a process in place to monitor either the appeal and grievance process or the areas of concern identified by enrollee appeals and grievances?

438.416 Recordkeeping and reporting requirements on grievances and appeals
1. To what extent is information on Medicaid enrollee grievances and appeals analyzed and included as part of your MCO's/PIHP's Quality Assessment and Performance Improvement Program?

Provider/Contractor Services Staff Interview

A. Description and Purpose

This is an interview of MCO/PIHP staff members who are responsible for establishing and maintaining communications with the MCO's/PIHP's individual practitioners and other types of health care providers (e.g., organizations). This includes staff responsible for management of the credentialing process and oversight of delegated activities. Through these interviews, assess the following:

1. The extent to which providers adequately address enrollee rights;

2. The manner in which the credentialing and appointment process is implemented;

3. Oversight of activities delegated to providers; and

4. Processes for providing information to providers.

B. Potential Questions to Ask

438.100 Enrollee rights
1. How does the MCO/PIHP inform its individual and institutional providers about enrollee rights and responsibilities? How does the MCO/PIHP monitor for compliance with these rights by its providers?

2. To what extent, if any, does the MCO/PIHP supply providers with information on where to refer enrollees who are having difficulty understanding the materials that have been provided to them by the MCO/PIHP?

3. Does the MCO/PIHP require providers to have access to oral interpreter services? Does the MCO/PIHP supply providers with guidance or assistance in accessing oral interpreter services if necessary?

4. How does the MCO/PIHP ensure that its own facilities and those of its affiliated providers comply with enrollee rights to treatment with respect, dignity, and consideration for privacy? Provide examples.

5. How does the MCO/PIHP ensure that enrollees are not discriminated against in its own facilities and those of its affiliated providers when seeking health care services consistent with their covered benefits?

6. Describe the MCO's/PIHP's credentialing and oversight process for primary care providers, other health care professionals and institutional providers. What is encompassed by reviews and evaluations of these providers? Do these processes involve visits to the providers' care delivery sites?

7. Are providers encouraged to share information on available treatment options and alternatives with enrollees? If so, what methods are used?

8. What processes are in place for monitoring providers to determine that they are providing information on available treatment options and alternatives?

9. What requirements does the MCO/PIHP have for providers/contractors relative to enrollee advance directives? How is it determined that providers/contractors are meeting the MCO's/PIHP's requirements?

10. How does the MCO/PIHP inform its individual and institutional providers about enrollee rights to service availability, coordination and continuity of care, coverage and authorization of service, and to obtain a second opinion from an appropriately qualified health professional? How does the MCO/PIHP monitor for compliance with these rights by its providers?

11. How are the MCO's/PIHP's network providers informed of enrollees' right to request and receive a copy of their medical records, and to request that they be amended or corrected?

12. What steps does the MCO/PIHP take to ensure that providers/contractors are aware of and in compliance with applicable Federal and State laws on enrollee rights?

13. If a provider/contractor is found in violation of any Federal and State laws on enrollee rights, what action is taken by the MCO/PIHP?

438.206 Availability of services
1. Describe the MCO/PIHP credentialing and recredentialing process. Is this different for Medicaid providers?

2. How is it determined that providers are geographically accessible to Medicaid enrollees and physically accessible to enrollees with disabilities?

3. Describe the processes for monitoring the provider network to determine that Medicaid requirements pertaining to timeliness, availability and accessibility are being met. What are the most recent findings from this process?

4. How often in the last year has your MCO/PIHP had to arrange for services or reimbursements to out-of -network providers?

438.206(c) Timely access to service

1. Are MCO/ PIHP and provider services available 24 hours a day, 7 days a week, when medically necessary?

2. Are the hours of operation of the provider network serving Medicaid enrollees different from the hours of operation of the provider network serving other enrollees? If yes, why are they different?

3. Does the MCO/PIHP continuously monitor its provider network for compliance with established standards on timeliness of access to all care and member services? If yes, how, and what are the most recent findings?

4. Is corrective action initiated when providers are not in compliance with established standards for timeliness of access to care and member services? Are the corrective actions assessed for effectiveness?

438.208 Coordination and continuity of care

1. How are primary care providers serving enrollees with special health care needs made aware of and involved in procedures for:
    - assessing these individuals?
    - ensuring that their treatment plans address the needs identified by the assessment?
    - Treatment planning, determining, and assuring appropriate use of specialists?
    - coordinating their care with care provided by other MCOs and PIHPs?

2. How are specialty providers serving enrollees with special health care needs made aware of and involved in procedures for:
    - assessing individuals with special health care needs?
    - ensuring that treatment plans address the needs identified by the assessment?
    - Treatment planning?
    - coordinating the care of individuals with special health care needs with the care provided by other MCOs and PIHPs serving the enrollee?

438.210 Coverage and authorization of services

1. Do contracts/agreements with individuals or organizations performing utilization review provide for any performance incentives? If yes, please describe the incentives. *[Note to reviewers: Look for any incentives for denying, limiting, or discontinuing authorization of services.]*

2. Are network providers notified of the information ordinarily required to process an authorization request?

3. Describe the process for notifying the requesting provider of any decision to deny, limit, or discontinue authorization of services. What are the MCO's/PIHP's time frames for notification?

438.214 Provider selection

1. What types of individual practitioners are subject to the MCO's/PIHP's credentialing process?

2. Describe the MCO's/PIHP's credentialing processes for individual practitioners. How often does this process take place? What items of credentials information are updated during the process? Are site visits made to providers? When and how often? How is it determined that a site visit will be made? Who is involved in the MCO's/PIHP's credentialing activities?

3. Describe the MCO's/PIHP's recredentialing processes for individual practitioners. What types of information are monitored and reviewed during the recredentialing process? What other operations of the MCO/PIHP contribute information to be used in the recredentialing process?

4. Describe the MCO's /PIHP's processes for selecting and monitoring institutional and other non- practitioner network providers. What information is reviewed as a part of this process? Are site visits made? When and how often?

5. Describe the MCO's/PIHP's credentialing and recredentialing processes for institutional providers. How frequently is re-credentialing performed? What items of information are typically reviewed during the evaluation and reevaluation process?

6. Are site visits a part of the process to credential and re-credential institutional providers?

7. What other MCO/PIHP operations contribute to the evaluation of a network institutional provider?

8. What criteria is the basis for denial of provider participation in the MCO's/PIHP's network?

438.228 Grievance systems

1. Describe the process for notifying the requesting provider of any decision to deny, limit, or discontinue authorization of services. What are the MCO's/PIHP's time frames for notification?

438.230 Sub contractual relationships and delegation

1. What types of activities are performed by (and thereby delegated to) contractors?

2. Describe your MCO's/PIHP's process for identifying and selecting contractors? How is it determined that a contractor has the ability to perform the activities that are being delegated by the organization?

3. What steps does your MCO/PIHP take to determine that an entity to which functions will be delegated is capable of performing the function? Describe any evaluation process that your MCO/PIHP has in place.

4. For <u>each</u> of the activities that have been delegated:
   - Is there any ongoing monitoring and review of entities performing delegated activities? How this is accomplished? Is the process the same for all delegates at all times? Are there any instances when your MCO/PIHP varies the monitoring process or the timing of evaluation?

   - Does your MCO/PIHP perform an annual evaluation of the delegate's performance? Describe the process undertaken to conduct this evaluation. What is included in the evaluation?

   - What is done with the results of delegate evaluations? Do the results of the most recent delegate evaluations specify any necessary corrective action for problems or deficiencies identified? Describe some of the recommendations made to delegates in an effort to improve performance.

   - What steps does your MCO/PIHP take to assure that the delegate implements corrective actions?

   - Who in the MCO/PIHP is assigned responsibility for monitoring the delegate's performance?

438.236 Practice guidelines
1. What mechanism is in place to consult affiliated providers as practice guidelines are adopted and re-evaluated?

2. How are practice guidelines disseminated to providers?

438.242 Health information systems
1. Does the MCO/PIHP have data collection requirements for health care facilities and physicians? How are the requirements relayed to these organizations and individuals?

2. If issues arise in the timeliness and accuracy of the data that is being collected and submitted, who notifies the health care facility or physician?

438.414 Information about the grievance system to providers and subcontractors
1. When are providers given information about the MCO's/PIHP's Medicaid complaint and grievance system? What is typically included in the information given to providers relative to Medicaid grievances?

Enrollee Services Staff Interview

A. Description and Purpose

The enrollee services staff interview provides an opportunity to talk with MCO/PIHP staff members who are responsible for communicating with enrollees. This includes those individuals responsible for: written communication, phone responses to inquiries and problems, the complaint and grievance system and other services designed to assist Medicaid enrollees in their use of MCO/PIHP services. Through this interview, assess the following:

1. The manner in which the MCO/PIHP and its provider network address issues relating to the rights of enrollees,

2. The MCO's/PIHP's efforts regarding enrollee education and communication,

3. The mechanisms in place to insure that information needed to provide services to enrollees is available throughout the MCO/PIHP, and

4. What aspects of enrollee services are measured, how collected data is assessed, and what efforts have been made to improve enrollee services.

B. Potential Questions to Ask

438.100 and 438.10 Enrollee right to information
1. What information is routinely provided to Medicaid enrollees? What is the process for disseminating information to new and existing enrollees? How often is information distributed to existing enrollees? In what format is this information presented?

2. Describe or provide copies of the formats in which information is presented to enrollees.

3. In what languages or alternative formats are enrollee materials and information presented? How was it determined that materials were needed in different languages?

4. Does the MCO/PIHP need written materials in alternative formats for the visually impaired? How did the MCO/PIHP determine this?

5. Describe the procedure for handling calls to the MCO/PIHP from non-English speaking enrollees. What instruction or guidance is available for providers that may need interpretation assistance to provide care and services to assigned enrollees?

6. To what extent is the MCO/PIHP responsible for responding to requests for information for potential Medicaid enrollees?

7. How does the MCO/PIHP inform enrollees (and potential enrollees, if applicable) about how to obtain oral interpreter services if they have limited proficiency in English?

9. Are there any benefits that an enrollee is entitled to under the Medicaid program, but that are not made available through the MCO contract? What are those benefits? How are the enrollees made aware of the Medicaid program benefits that are outside the scope of services available through the MCO?

10. How does the MCO/PIHP ascertain the primary language spoken by the individual Medicaid enrollees?

11. Are enrollees provided with a listing of primary care providers? Does the listing include providers' non-English language capabilities?

12. Does your MCO/PIHP give written notice of termination of a contracted provider to enrollees who receive primary care from, or are seen on a regular basis by, the terminated providers? How is this accomplished? Have you had to make any such notifications in the last year?

13. Does your MCO/PIHP give enrollees any notice of significant changes change in the information specified above? When and how does this occur? Have you had to make any such notifications in the last year?

438.100 Enrollee right to respect . . . dignity, and . . . privacy
1. How does the MCO/PIHP ensure that its own facilities and those of its affiliated providers comply with enrollee rights to treatment with respect, dignity, and consideration for privacy? Provide examples.

438.100 Enrollee right to participate in decisions regarding his or her health care and 438.10(g) regarding advance directives
1. To what extent does the MCO/PIHP allow enrollees to participate in care and treatment decisions? Describe some of the ways in which this is accomplished.

2. To what extent are Medicaid enrollees informed at the time of enrollment of their right to accept or refuse treatment and to execute an advance directive and the MCO's/PIHP's policies on implementation of that right?

438.100 Enrollee right to service availability, coordination and continuity of care, coverage and authorization of service, and to obtain a second opinion from an appropriately qualified health professional
1. How does the MCO/PIHP monitor for compliance with enrollee rights to service availability, coordination and continuity of care, coverage and authorization of service, and to obtain a second opinion from an appropriately qualified health professional? What are the most recent results of this monitoring?

438.100 Enrollee right to request and receive medical records

1. How do enrollees obtain access to their medical records maintained by the MCO/PIHP, including records maintained by providers/contractors from whom the enrollee has received services?

2. How are enrollees informed of their right to request and receive a copy of their medical records, and to request that they be amended or corrected?

3. Has the MCO/PIHP received any complaints about an enrollee's inability to timely access their medical records? If yes, what was the volume and nature of the complaints? How were they resolved?

438.100 Compliance with other Federal and State laws
1. Does the MCO/PIHP orient staff to the Federal and State laws on enrollee rights that must be observed during day-to-day operations? Does the MCO/PIHP remind staff of the importance of observing these laws during interactions with other employees and with enrollees?

2. Describe the procedure for handling an enrollee complaint involving a perceived violation of their rights.

438.206 Availability of services
1. What processes does the MCO/PIHP take to monitor availability and accessibility of services to Medicaid enrollees? What are the most recent findings from this process?

2. Is there any information that is routinely collected and monitored to determine that care and services are being rendered to Medicaid enrollees in a timely manner? What are the most recent findings of this monitoring?

438.206(b) Availability of services-Delivery network
1. Are Medicaid enrollee requests for out-of-network providers tracked? How often do Medicaid enrollees request services from out-of-network providers? What are their reasons for requesting out-of-network providers?

2. How often do Medicaid enrollees receive services from out-of-network providers?

438.206(c) Availability of services-Furnishing of services
1. Are MCO/ PIHP and provider services available 24 hours a day, 7 days a week, when medically appropriate?
2. How frequently does enrollee services staff receive complaints about provider hours of operations not being available to enrollees when medically necessary?

3. Does the MCO/PIHP conduct surveys, focus groups or other activities to receive the feedback of Medicaid enrollees? If so, what are the most recent findings about Medicaid enrollee perceptions about availability of MCO/PIHP and provider services?

438.208 Coordination and continuity of care
1. Does this MCO/PIHP screen Medicaid enrollees to identify those with special health care needs? If yes, how is this implemented?

2. How are Medicaid enrollees with special health care needs - including both any individuals with special health care needs identified by your MCO/PIHP and any identified by the State Medicaid agency or its agent - identified and tracked within your MCO/PIHP?

3. Does this MCO/PIHP assess Medicaid enrollees with special health care needs? If yes, how are these activities conducted?

4. What proportion of Medicaid enrollees has an ongoing source of primary care?

5. What proportion of Medicaid enrollees has a person or entity formally designated as primarily responsible for coordinating their health care services?

6. What proportion of Medicaid enrollees with special health care needs has a person or entity formally designated as primarily responsible for coordinating their health care services?

438.210 Coverage and authorization of services
1. How frequently does enrollee services staff receive complaints about difficulty obtaining emergency or post-stabilization services?

2. Describe the procedure for handling member calls regarding need for emergency services.

438.226 Enrollment and disenrollment

1. Describe the procedures that are followed when a request for disenrollment is received from an enrollee.

2. Is disenrollment information tracked through or by other MCO/PIHP operations (e.g., grievance process, quality improvement, administration)? How many requests by Medicaid enrollees were received last year for disenrollment? What were the cited causes?

438.228 Grievance systems

1. Describe the process for notifying Medicaid enrollees of any decision to deny, limit, or discontinue a request for service. What are the MCO's/PIHP's time frames for notification?

438.236 Practice guidelines

1. How often does your MCO/PIHP receive requests from enrollees and potential enrollees for practice guidelines? How does your MCO/PIHP respond to these requests?

2. When and how does your MCO/PIHP disseminate practice guidelines to enrollees?

438.402 Grievance system - general requirements

1. What enrollee materials contain information about the complaint and grievance processes? When are enrollees presented with this information?

2. Describe the process for handling authorization decisions that are adverse to the enrollee.

438.406 Handling of grievances and appeals

1. What MCO/PIHP department or staff members are responsible for assisting enrollees to use the organization's complaint or grievance system, including completing forms, or taking other steps to resolve an appeal or grievance? What kind of assistance is made available to Medicaid enrollees?

2. What are the qualifications and credentials of individuals who make decisions on grievances and appeals? How does the MCO/PIHP ensure that these individuals:
    - were not involved in any previous level of review or decision-making; and
    - if deciding any of the following, have the appropriate clinical expertise in treating the enrollee's condition or disease.
        (A) An appeal of a denial that is based on lack of medical necessity.
        (B) A grievance regarding denial of expedited resolution of an appeal.
        (C) A grievance or appeal that involves clinical issues?

3. How does your MCO/PIHP treat oral requests by Medicaid enrollees to appeal actions?

4. As part of an appeal, to what extent do enrollees and their representatives have an opportunity to:
    -   Present evidence and
    -   examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.

438.408 Resolution and notification: Grievances and appeals

1. Describe the MCO's/PIHP's grievance resolution process.

2. Describe the MCO's/PIHP's appeal resolution process. Are Medicaid enrollees required to exhaust the MCO's/PIHP's internal appeals process before seeking and receiving a State fair hearing?

3. How is it determined that an enrollee's appeal requires expedited resolution?

4. What percent of appeal resolutions that are completely or partially adverse to Medicaid enrollees are appealed to the State fair hearing process? Of these, what percent are overturned by the State Medicaid agency?

438.410 Expedited resolution of appeals
1. Is there a process in place for those instances when an enrollee's health condition requires expedited resolution of an appeal? Describe this process. What are the time frames defined for this process?

2. How does the MCO/PIHP notify enrollees of any denials of a request for expedited resolution?

3. Have there been any complaints by Medicaid enrollees that their requests for expedited appeals have not been acted upon timely (e.g., within three working days). If so, how many such complaints were received in the year under review?

438.416 Recordkeeping and reporting requirements
1. How are Medicaid grievances and appeals registered and tracked for resolution? Is each grievance and appeal tracked through to resolution?

2. How often is Medicaid grievance and appeal information analyzed for trends? Who receives this analysis? Does the MCO/PIHP provide any information to the State relative to its grievances and appeals?

3. How long are Medicaid grievance and appeal records retained?

4. To what extent is information on Medicaid enrollee grievances and appeals analyzed and included as part of your MCO's/PIHP's Quality Assessment and Performance Improvement Program?

438.420 Continuation of benefits while the MCO or PIHP appeal and the State Fair hearing are pending
1. What happens to enrollee benefits once continuation of benefits has been denied by the MCO/PIHP, and an appeal has been filed by the enrollee or the treating physician? Are there any mechanisms in place to continue the benefits pending the outcome of the appeal? If so, under what circumstances?

Utilization Management Personnel Interview

A. Description and Purpose

The utilization management interview provides an opportunity to assess the processes used to ensure the following:

- Service authorization;
- Use of practice guidelines;
- Responsiveness to grievances and appeals; and
- The management of resources across all MCO/PIHP network provider sites where enrollees receive health care.

MCO/PIHP interview participants should include the Medical Director, utilization management directors or managers, utilization management review staff, case managers or care coordinators, and any other individuals who have information pertinent to these regulatory provisions.

[Note: This interview can be combined with the Medical Director interview or the Care Coordinators and Case Managers interview.]

B. Potential Questions to Ask

438.206(b) Delivery network
1. What procedures must a Medicaid enrollee follow if he/she wishes to receive a second opinion? For what types of services are second opinions available?

438.210 Coverage and authorization of services
1. What types of services require pre-authorization?

2. What are the MCO's/PIHP's time frames for processing standard and expedited requests for service authorization?

3. How does the MCO/PIHP monitor its compliance with these time frames? What sources of documentation exist to provide evidence of the monitoring by the MCO/PIHP?

4. How often and under what circumstances are requesting providers consulted when the MCO/PIHP makes service authorization decisions?

5. To what extent does the MCO/PIHP assess the consistency of authorization decisions? How does the MCO/PIHP do this?

6. What is the process when a decision is being made to deny authorization for a service? Who makes the decision to deny a request to authorize a service?

7. Describe the process for notifying the requesting provider and the enrollee of any decision
to deny, limit, or discontinue authorization of services. What information is typically included in enrollee and provider notification? What are the MCO's/PIHP's time frames for notification?

8. How big of a problem is inappropriate use of emergency rooms by your Medicaid enrollees?

9. Has your MCO/PIHP investigated a potential relationship between inappropriate emergency room use and enrollee access to routine and urgent care?

10. What was the volume of denied claims for emergency and post-stabilization services in the most recent year?

438.228 Grievance systems
1. What types of services require pre-authorization?

2. Describe the process for notifying the requesting provider and the enrollee of any decision to deny, limit, or discontinue authorization of services. What information is typically included in enrollee and provider notification? What are the MCO's/PIHP's time frames for notification?

3. How does your MCO/PIHP track requests for covered services that your MCO/PHP or its providers has denied?

4. What was the volume of denied request for services in the most recent year?

438.236(c) Application of practice guidelines
1. What practice guidelines have your MCO/PIHP adopted?

2. To what extent are your utilization management review guidelines (criteria) consistent with these practice guidelines? How do you promote or ensure consistency?

3. Describe how utilization management review guidelines (criteria) are modified to reflect the adoption or revision of practice guidelines. Are both sets of guidelines updated through the same process, at the same time?

438.240 Quality assessment and performance improvement program
1. What information is analyzed to detect over- and under-utilization of services? Who is involved in the analysis and review of this information? Have any trends been identified? What are the typical follow-up actions taken when either condition is discovered?

438.402 Grievance system - General requirements
1. Describe the appeals process and the role of utilization management staff in the resolution process. Elaborate on the particular steps, including time frames, in which utilization management staff is involved.

2. Is there a process in place for those instances when an enrollee's health condition requires expedited resolution of an appeal? Describe this process and its time frames.

438.406 Handling of grievances and appeals
1. What MCO/PIHP department or staff are responsible for assisting enrollees in using the MCO's/PIHP's appeal or grievance system, including completing forms, or taking other steps to resolve an appeal or grievance?

2. What are the qualifications and credentials of individuals who make decisions on grievances and appeals? How does the MCO/PIHP ensure that these individuals:
   - were not involved in any previous level of review or decision-making; and
   - If deciding any of the following, have the appropriate clinical expertise in treating the enrollee's condition or disease.
      (A) An appeal of a denial that is based on lack of medical necessity.
      (B) A grievance regarding denial of expedited resolution of an appeal.
      (C) A grievance or appeal that involves clinical issues?

438.410 Expedited resolution of appeals
1. Is there a process in place for those instances when an enrollee's health condition requires expedited resolution of a grievance? Describe this process. What are the time frames defined for this process?

2. How does the MCO/PIHP notify enrollees of any denials of a request for expedited resolution?

438.420 Continuation of benefits while the MCO or PIHP appeal and the State Fair Hearing are pending
1. What happens to enrollee benefits once continuation of benefits has been denied by the MCO/PIHP, and an appeal has been filed by the enrollee or the treating physician? Are there any mechanisms in place to continue the benefits pending the outcome of the appeal? If so, under what circumstances?

Medical Director Interview

A. Description and Purpose

The interview with the Medical Director provides an opportunity to assess MCO/PIHP processes for authorizing services and coverage for those services. The interview will address such topics as provider involvement in the review of criteria used in the utilization management process, consistency between utilization management criteria and practice guidelines, and QAPI efforts.

[Note: This interview can be combined with the Utilization Management interview or the Care Coordinators and Case Managers interview.]

B. Potential Questions to Ask

438.210 Coverage and authorization of services

1. How does the MCO/PIHP monitor its compliance with the State's time frames for processing standard requests for service authorization?

2. What are the MCO's/PIHP's standards for processing expedited requests for service authorization? How does the MCO/PIHP monitor its compliance with these time frames?

3. Under what circumstances is there consultation with requesting providers when responding to service authorization requests?

4. How does the MCO/PIHP ensure consistent application of criteria used in making service authorization decisions?

5. What mechanism does the MCO/PIHP use to assure that any decision to deny a service authorization request or to authorize a service in an amount, duration or scope that is less than requested, be made by a health care professional who has appropriate clinical expertise in treating the enrollees' condition or disease?

6. How are employees and any contractors used by the MCO/PIHP to perform service authorization and utilization management financially compensated? Are they paid in any way other than on a straight salary or per case review basis? Do their financial compensation arrangements involve the use of any financial incentives?

438.240 Quality assessment and performance improvement program

1. Does the MCO/PIHP have any processes for reviewing claims, payment systems, encounter data, and medical records to assess utilization of services? What reports on service utilization are regularly produced by these processes? What are the most recent findings with respect to over- and under-utilization?

2. How does your MCO/PIHP define enrollees with "special health care needs"? How are these enrollees identified within your MCO/PIHP?

3. How does your MCO/PIHP assess the quality and appropriateness of care furnished to enrollees with special health care needs? Provide examples.

Case Managers and Care Coordinators Interview

A. Description and Purpose

Case managers and care coordinators typically are among the few MCO/PIHP staff with opportunity to interact closely and directly with Medicaid enrollees. These individuals are often responsible for guiding enrollees to the care and services available through their benefits and the provider network. These individuals play a key role in assisting enrollees in managing and maintaining their health and managing complex conditions. Interviewing these individuals will provide reviewers the opportunity to discuss topics surrounding MCO/PIHP processes related to:
   o   Availability of services,
   o   Assessment of enrollees needs,
   o   Services available to women,
   o   Services offered to enrollees with special health care needs, and
   o   Continuity and coordination of enrollee health care.

[Note: This interview can be combined with the Medical Director interview or the Utilization Management interview.]

B. Potential Questions to Ask

438.100(b)(iv) Enrollee right to participate in decisions regarding his or her health care
   1.   To what extent does the MCO/PIHP allow enrollees to participate in care and treatment decisions? Describe some of the ways in which this is accomplished.

438.206(c) Furnishing of services and timely access
   1.   To what extent are services offered through the MCO/PIHP available to Medicaid enrollees and others coordinating care 24 hours per day, 7 days per week when medically necessary?

   2.   What types of services require pre-authorization?

438.208 Coordination and continuity of care
   1.   Does this MCO/PIHP screen Medicaid enrollees to identify those with special health care needs? If yes, how is this implemented?

   2.   How are Medicaid enrollees with special health care needs - including both any individuals with special health care needs identified by your MCO/PIHP and any identified by the State Medicaid agency or its agent - identified and tracked within your MCO/PIHP?

   3.   Does this MCO/PIHP assess Medicaid enrollees with special health care needs? If yes, how are these activities conducted?

4. Does this MCO/PIHP require written treatment plans to be developed for enrollees with ongoing special conditions that require a course of treatment or regular care monitoring? If yes, how is it decided which Medicaid enrollees will receive a written treatment plan?

5. If treatment plans are required by this MCO/PIHP, how does the MCO/PIHP ensure that treatment plans for individuals with special health care needs address the needs identified by the assessment?

6. Describe the treatment planning process for individuals with special health care needs and the process for determining and assuring appropriate use of specialists.

7. Within the last year, how many treatment plans have been developed? How many requests for treatment plans have been denied? What were the reasons for these denials? How many treatment plans have been denied?

8. What process(es) is/are used to coordinate services for enrollees? Are their different types of care coordination mechanisms for different types of enrollees? If so, how are these different and how do they work?

9. Who is responsible for coordinating the care of individuals with special health care needs?

10. What are the procedures for coordinating the services that the MCO/PIHP furnishes to the enrollee with services the Medicaid enrollee receives from any other MCOs and PIHPs?

11. If the MCO/PIHP establishes separate coordination of care for medical services and mental health and substance abuse services, how does the MCO/PIHP ensure exchange of necessary information between providers?

438.210 Coverage and authorization
1. What types of services require pre-authorization?

Providers and Contractors Interview (Optional)

A. Description and Purpose

Interviewing providers and contractors requires additional time and resources. However, it is an opportunity to obtain further information about MCO/PIHP performance from those health care professionals and institutions that often serve as the first point of contact for Medicaid members and health care providers. Because of this, provider and contractor interviews should be considered as an optional component of this protocol - to be considered whenever there is a strong need for additional information and when time and resources permit.

The provider network is the source of interview participants. Participants should be selected to give, as much as possible, a representative view of the breadth of the MCO's/PIHP's primary care, specialist, and institutional providers. Discussions with providers and contractors can often clarify issues pertaining to:
- o Communication,
- o Movement of enrollees through the MCO/PIHP system,
- o Observance of enrollee rights, and
- o Information required providing care and services to enrollees.

The interview can be arranged with a group of individual health care practitioners and with a group of institution representatives. It can be coordinated as one interview for each group or as a combined group. Geographic location of providers should be considered, and conference calls are a viable option for conducting an interview of this type, and often preferred by providers as only a brief interruption in their daily activities. In order for this interview to be effective, reviewers are reminded to emphasize with providers that this is not an evaluation of the care and services they offer to Medicaid enrollees, but rather their opportunity to provide insight on the MCO's/PIHP's performance.

B. Potential Questions to Ask

438.100 Enrollee rights and 438.10 Enrollee information
1. When the MCO's/PIHP's enrollees present for services, do they appear to have a clear understanding of their rights, responsibilities, and benefits? How to obtain services?

2. Does the MCO/PIHP provide you with information on where to refer enrollees who are having difficulty understanding the materials that have been provided to them by the MCO/PIHP?

3. How often do you and your staff have to assist enrollees with understanding the materials provided by the MCO/PIHP?

4. Does the MCO/PIHP require providers to have access to oral interpreter services? Does the MCO/PIHP provide your office with guidance or assistance is accessing interpreter services if necessary?

438.100 Enrollee rights to receive information on available treatment options and 438.102 Provider-enrollee communications
1. Does the MCO/PIHP place any limits on your ability to counsel or advise a Medicaid enrollee on treatment options that may be appropriate for the enrollee's condition or disease?

2. Does the MCO encourage providers to share with enrollees information on available treatment options and alternatives? Does this include options and alternatives that are within as well as those outside the scope of the enrollees benefits? If so, how does the MCO/PIHP do this?

438.206(c) Availability of Services: Furnishing of services
1. Are your hours of operation for Medicaid enrollees different from the hours of operation for other MCO/PIHP enrollees? If so, why?

438.236 Practice guidelines
1. Are affiliated providers/contractors consulted as practice guidelines are adopted and re-evaluated?

2. How does the MCO/PIHP make providers/contractors aware of practice guidelines currently in use and those under consideration for adoption?

438.410 Expedited resolution of appeals
1. Have there been any instances in the most recent year under review when the MCO/PIHP took any punitive action against you for requesting an expedited resolution of an appeal on behalf of Medicaid enrollees or for supporting an enrollee's appeal?

ACTIVITY 5:   Collecting accessory information

Sometimes information is needed that cannot be collected from interviews and review of MCO/PIHP internal documents. In these situations, it is necessary to pursue information from other sources. Such sources might include:

- Results of Medicaid beneficiary surveys
- Results of independent assessments of the MCO's/PIHP's information systems
- Results of independent assessments of MCO/PIHP encounter data, or
- Results of independent validations of MCO/PIHP performance measures or improvement projects

Reviewers will take notes when they review any such information sources and identify any information pertaining to MCO/PIHP compliance with the regulatory provisions. These findings will be transferred to a documentation and reporting tool such as that found in Attachment C.

ACTIVITY 6: Analyzing and compiling findings

Completing the Documentation and Reporting Tool

Reviewers will be taking notes during document review, interview, and accessory activities. These notes will need to be translated into compliance determinations for each regulatory provision. This protocol includes sample documentation and reporting tool in Attachment C that can be used to convert reviewer notes into findings. Reviewers should use this or a similar tool to document their findings. Once completed, the tool serves as a comprehensive record of review activity.

The documentation and reporting tool in Attachment C is presented in numerical order by Proposed Rule requirement. Regulatory provisions appear in the left column of the tool. The provisions are divided into individual components, when possible, so that reviewers may identify specific aspects of the regulation that a MCO/PIHP may only partially meet or not meet at all. There are three columns on the right side of the tool for reviewers to check a designation of Met, Partially Met, or Not Met (however, an EQRO can use as many compliance categories as the State determines appropriate-see below). These determinations will be based on reviewer notes taken throughout the onsite evaluation.

When reviewers select a designation of Partially Met or Not Met for any of the regulatory provisions, documentation should be supplied to explain the MCO's/PIHP's deficiency. The documentation should be written in such a way that any audience viewing the reporting tool could identify the specific deficiency. Documentation fields are not provided for each individual component of the regulatory provision, but rather for a group of related components or the provision in its entirety.

Reviewers can use the reporting tool as both a guide and a form for directly recording information when performing the onsite evaluation. However, this may be difficult, as the regulatory provisions are not grouped by topic, documents, or type of MCO/PIHP operations.

Summarizing Findings

Analysis and presentation of findings from the evaluation of an MCO/PIHP will be highly dependent on the audience. While non-summarized findings might be of interest to some individuals, other parties might prefer a summary of the findings or information about compliance with specific regulatory provisions.

One commonly used approach to summarizing an evaluation is to assign a numerical value to the findings. A numerical scale can be used to indicate the degree of compliance with a given regulatory provision. The documentation and reporting tool in Attachment C has been designed to allow reporting of findings for (1) one, (2) multiple, or (3) larger combinations of regulatory requirements. Each regulatory provision can be assigned a rating, which can be combined with ratings of related regulatory provisions, which in turn can be combined with ratings of other groups of regulations, and eventually into a single compliance rating for the MCO/PIHP. The

degree of "roll-up" or aggregation will be determined by the detail of reporting that the State Medicaid agency expects relative to the regulatory provisions.

Rating scales can be established for all four levels described above. Each scale can be designed to build upon the last level, or can be developed independently of the others. Some common rating or scoring systems include:

Two-point rating or scoring - Either the requirement is met or is not met in the evaluation.

    1 - Met
    2 - Not Met

Three-point rating or scoring - This scale allows for credit when a requirement is partially met, if this level of performance is acceptable.

    1 - Fully Met
    2 - Partially Met
    3 - Not Met

Five point rating or scoring - One of five levels of compliance could be noted, allowing for greater sensitivity to the potential levels of performance, especially in complex performance areas.

    1 - Fully Met
    2 - Substantially Met
    3 - Partially Met
    4 - Minimally Met
    5 - Not Met

While one rating or scoring scale may serve as the primary system, it does not necessarily preclude the combined use of all the noted alternatives. While a five-point scale may be appropriate to use for most of the provisions, there may be instances when a provision or component of a provision cannot be partially met.

The State Medicaid agency will need to identify how much compliance detail it requires, and what rating or scoring system is to be used at each point of summary to designate a level of compliance. The significance of the rating or scoring system must be clearly defined to avoid any confusion about the meaning of summarized data.

Defining Compliance with Regulatory Provisions

Thresholds for compliance or non-compliance determinations with each regulatory provision or component of a provision should be specified by the State Medicaid agency, based on its expectations of MCO/PIHP performance. For example, the agency may decide that full compliance is defined as any of the following:

- All documentation listed under a regulatory provision, or component thereof, must be present (that is, if only one item is not available, the MCO/PIHP is considered "Not compliant"); and

- MCO/PIHP staff are able to provide responses to reviewers that are consistent with each other, and with the documentation; or

- A percentage of data sources (i.e., documents and individuals interviewed able to provide evidence of compliance with regulatory provisions) can be established and used as the threshold for determining what constitutes "full compliance."

Partial compliance could be determined as:

- There is compliance with all documentation requirements, but staff are unable to consistently articulate processes during interviews; or

- Staff can describe and verify the existence of processes during interview, but documentation is found incomplete or inconsistent with practice; or

- Any combination of "Met," "Partially Met" and "Not Met" findings at the components of a regulatory provision would result in a "Partially Met" designation for the provision as a whole.

No compliance could be defined as:

- No documentation is present and staff have little to no knowledge of processes or issues addressed by the regulatory provisions; or

- For those provisions with multiple components: Key components of the provision could be identified, and any findings of Not Met or Partially Met would result in an overall provision finding of no compliance, regardless of the findings noted for remaining components.

The State Medicaid agency can establish thresholds for performance at different levels of regulatory provisions (e.g., individual regulations, a group of related regulatory provisions, and for all regulatory provisions combined), depending on the intended use of the evaluation results. Both Attachment B and the documentation and reporting tool Attachment C supplied with this protocol currently separate the regulatory provisions into four major sections:

Enrollee Rights, Access, Measurement and Improvement, and Grievance System. State Medicaid agencies may want to break these major sections down even further to focus in on specific aspects or components of the regulatory provisions to make performance improvement more manageable and targeted. For example, an agency may determine that MCOs/PIHPs must demonstrate the following levels of compliance, which look at two levels of summary, the major section and one level below at each regulatory provision:

1. Under the Enrollee Rights heading: 5 of the 7 Regulatory Provisions (in their entirety) must have findings of "Met" and the remainder must have findings of "Partially Met."

2. Under the Access heading: 10 of the 16 Regulatory Provisions (in their entirety) must have findings of "Met" and the remainder must have findings of "Partially Met."

3. Under the Measurement and Improvement heading: All three (3) regulatory provisions (in their entirety) must have findings of "Met."

4. Under the Grievance System heading: 8 of the 10 regulatory provisions (in their entirety) must have findings of "Met" and the remainder must have findings of "Partially Met."

The State Medicaid agency will need to consider all the uses for the MCO/PIHP evaluation in establishing rules to guide the compliance scoring and determination. Pre-planning for the use of results will be vital to implementation of an effective evaluation process.

Reporting Evaluation Results to the MCO/PIHP

Upon completion of a performance evaluation it is common practice to share the results with the subject, in this case the MCO/PIHP. There are a number of alternative strategies for reporting evaluation results to the MCO/PIHP. The State Medicaid agency will need to determine the method for reporting results to the MCO/PIHP that best serves its purpose. Following are four possible alternatives for reporting.

- Alternative One - Reviewers do not share findings with the MCO/PIHP, deferring to the report the MCO/PIHP will receive from the State following review of the evaluation outcome. This may take the form of reporting performance deficiencies with requests for MCO/PIHP corrective action.

- Alternative Two - Reviewers report compliance issues (but not individual regulatory provision compliance determinations) they have identified during the course of the evaluation. There is an opportunity for the MCO/PIHP to offer additional information, if such evidence of compliance is available. There is no attempt to aggregate findings or indicate any MCO/PIHP overall "level of performance" on the regulatory provisions. This <u>verbal</u> report would usually be presented at the conclusion of the onsite evaluation during a closing session with MCO/PIHP leadership.

- Alternative Three - Reviewers <u>verbally</u> discuss the findings that resulted in determinations of less than full compliance (This alternative would require that the reviewers have knowledge of the thresholds determined to arrive at these conclusions, as determined by the State Medicaid agency.) The MCO/PIHP would be able to provide further evidence of compliance, assuming such is available. No overall judgement regarding performance of the MCO/PIHP would be offered. This discussion would occur in the same format as described in alternative two.

- Alternative Four - In addition to discussing specific compliance issues (as above), the reviewers would indicate an overall compliance finding or rating, based on aggregation of all the regulatory provisions. Reviewers would highlight those areas of deficiency that will be presented to the State Medicaid agency. The aggregation process would be based on the State's established thresholds. Presentation of findings would occur in the same format as described in alternative two, but could also involve leaving a written report with the MCO/PIHP.

ACTIVITY 7: Reporting evaluation results to the State Medicaid Agency

Outlining State Medicaid Agency reporting needs is an important planning step and should be factored into all decisions that are made relative to Activity 6, Analyzing and Compiling Findings. State Medicaid agencies must carefully consider the types of information requests they must be responsive to relative to the Medicaid managed care program. These requests can be made by federal or state government agencies, the state legislature, local advocacy groups, as well as other interested parties. If the regulatory provision evaluation process is a source for this information, it is important that a system of analyzing and compiling findings support these requests.

Following are some of the possible alternatives for reporting compliance evaluation findings to the State Medicaid agency. Reporting alternatives are heavily dependent on the decisions made at Activity 6. That is, if findings are not summarized in some manner according to compliance definitions, groupings of regulatory provisions, etc., reporting to the State Medicaid Agency will be limited.

- Alternative One - The documentation and reporting tool, reflecting reviewer findings, is submitted to the State Medicaid agency without further analysis by the entity responsible for evaluation activity. Decisions relative to compliance would be made by the State Medicaid agency.

- Alternative Two - The entity responsible for the evaluation would complete a narrative summary of reviewer findings as documented on the documentation and reporting tool for each MCO/PIHP, (summary of the information contained in the documentation and reporting tool) with simple analysis, such as the total number of regulatory provisions with a status of Met, Partially Met, and Not Met. Regulatory provision compliance determinations and decisions would rest with the State Medicaid agency.

- Alternative Three - Based on State Medicaid agency established thresholds and compliance guidelines, the entity responsible for the evaluation would aggregate or summarize reviewer findings noted on the documentation and reporting tool for each MCO/PIHP. These would be submitted to the State Medicaid agency for making regulatory provision compliance determinations.

- Alternative Four - The entity responsible for the evaluation would present all the reporting noted above and additionally an overall compliance summary and determination for the MCO/PIHP. The compliance summary would be based on pre-established State established thresholds and guidelines.

The State Medicaid Agency may desire a report that demonstrates how all plans performed when evaluated for compliance with the regulatory provisions. The above noted alternatives will accommodate this type of report, with some being more succinct and easier to produce than others are. The State Medicaid Agency may choose alternatives other than those described above.

END OF PROTOCOL